

REMARKS

Claims 18-20 and 32-38 are currently pending in this patent application.

Rejection under 35 U.S.C. § 103 – Alleged Obviousness

Claims 18-20, 32, 33, 35-36, and 38 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over U.S. Patent No. 5,248,310 (“the Barclay patent”) in view of U.S. Patent No. 5,785,994 (“the Wong patent”) in further view of U.S. Patent No. 5,294,770 (“the Riddle patent”). Applicants respectfully traverse the rejection because combination of the respective teachings of these patents, even if motivated, would not have produced any claimed method.¹ Specifically, the Office Action fails to provide any evidence or rationale supporting the contention that “combination of the cited references does indeed form a drug/drug/no drug orientation three-layer tablet structure” (Office Action at page 7).

The Office Action does not dispute that the dosage form disclosed by the Wong patent is fundamentally different from those recited in the instant claims. As Applicants previously noted, although the Wong patent discloses a three-layer dosage form, the orientation of those layers differs from the orientation recited in the instant claims (*see* Wong, FIG. 3, disclosing a three-layer dosage form having an osmoagent layer 18, a drug layer 22, and an osmotic push layer 24; *see also* Wong at column 17, lines 34-43, describing a “no drug/drug/no drug” structure that is said to be formed by disposing a *single* drug-containing layer between two layers that do not contain a drug). The Wong patent does not disclose the use of two drug layers, as recited in Applicants’ rejected claims.

¹ With respect to the issue of motivation, the Office Action continues to misstate the requirements for establishing a *prima facie* case of obviousness. Although the Office Action asserts that it would have been obvious to combine the teachings of the Barclay, Wong, and Riddle patents “because the ordinary [person having] skill in the art would have had a reasonable expectation of success” (Office Action at page 6), much more is required to support a rejection under Section 103. Specifically, an examiner seeking to enter a rejection for alleged obviousness must additionally identify some suggestion or motivation to combine references or otherwise modify their teachings. MPEP § 2142.

The Office Action similarly does not dispute that there is no disclosure in the Barclay patent of a dosage form having two drug layers. Although that patent teaches a two-layer dosage form, only *one* of the layers contains drug.

The remaining cited reference does not remedy the above-noted deficiencies. Indeed, the Riddle patent is relied upon solely for its disclosure relating to the use of a color detector to orient tablet formulations during their manufacture (Office Action at page 6).

Thus, there is no reason to believe that a person of ordinary skill who had knowledge of the cited references would have combined their respective teachings in a way that would have produced a claimed method. Indeed, absent the hindsight that is provided by Applicants' own disclosure, there is no reason to believe that a person of ordinary skill would have even been motivated to even attempt such a combination.

The Office Action appears to mistakenly suggest that claims may be rejected for alleged obviousness so long as they are directed to subject matter that those skilled in the art would be able to practice (Office Action at page 7).² A claimed invention, however, may not be found obvious simply because it can be practiced by those skilled in the art; were that not the case, no invention that complies with the enablement requirement of 35 U.S.C. § 112 would ever be patentable. Rather, claims may be found obvious only if those of ordinary skill (without the benefit of Applicants' own disclosure) would have been motivated to modify the teachings in the prior art in a way that would have produced the claimed subject matter. *See* M.P.E.P. § 2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Since Applicants have demonstrated that combination of the respective teachings Wong, Barclay, and Riddle patents would *not* have produced any method within the scope of the pending claims, the rejection for alleged obviousness is improper and should be withdrawn. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (all limitations set

² "However, preparing a two or three layer osmotic tablet [is] well within the level of an ordinary skill in the art."

DOCKET NO.: ALZA-0022 / ARC-2865 R3
Application No.: 09/324,343
Office Action Dated: January 17, 2007

**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

forth in a patent claim must be taught or suggested in the prior art to establish a *prima facie* case of obviousness).

Conclusions

In view of the above, applicants respectfully request reconsideration and withdrawal of the rejection of claims 18-20, 32, 33, 35-36, and 38, as well as allowance thereof. If the Examiner is of a contrary view, the Examiner is invited to contact the undersigned attorney at (215) 568-3100.

Date: April 13, 2007

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